properties.

32. (Amended) The dosage form of Claim 23 that dissolves in the mouth without need for drinking water or other fluid.

33. (Amended) The dosage form of Claim 23 that is a breath-freshening pastille.

34. (Amended) The dosage form of Claim 23 that is a chewing gum.

35. (Amended) The dosage form of Claim 23 that is a sublingual tablet.

36. (Amended) The dosage form of Claim 23 that is a mucoadhesive film.

37. (Amended) The dosage form of Claim 23 that is an oral strip.

38. (Amended) The dosage form of Claim 23 that is an oral fast-melt tablet.

REMARKS

Applicant has made a statement (page 2 line 17 of the specification as filed) that could be interpreted to mean that WO 00/40226 provides no information as to the route of administration of its subject compounds. This statement was made without deceptive intent and indeed is true of the particular prescription referenced at page 2 lines 12–16 of the present specification. However, it is noted that WO 00/40226 makes the general statement at page 6 lines 12–14 thereof that its subject compounds "... in the known appropriate pharmaceutical dosage form for a given route of administration may be administered orally, intra-nasally, buccally, intra-pulmonary *[sic]*, parenterally and rectally." Beyond this general statement no information is provided on nature of dosage form in WO 00/40226.

Accordingly, amendment of the paragraph beginning at page 1 line 21 is requested to remove any suggestion that no information is provided in WO 00/40226 as to the route of administration, while retaining the indication that no information is provided therein as to the specific nature of dosage form.

Amendment of independent Claims 1 and 23 are requested to focus these claims on a presently preferred embodiment of the invention wherein the dosage form is an oral dosage form selected from the group consisting of fast-melt formulations, breath-freshening pastilles, chewing gums, sublingual tablets, mucoadhesive films and oral strips. Support for this Markush group of oral dosage forms is found in the specification at least at page 15 lines 7–9. In amending Claims 1 and 23 to add recitation of this Markush group, the phrase characterizing the dosage form as "being adapted for delivery by a route of administration that

entails interaction with the organs of taste" has been deleted, it being noted that all classes of dosage form in the added Markush group are inherently so adapted.

Claims 10–15 and 26–31 are cancelled as (a) being drawn to subject matter no longer embraced by the independent claims as amended herein or (b) failing to further limit the subject matter of the independent claims as amended herein. Applicant reserves the right to reintroduce in a later continuation or divisional application the subject matter of any claim cancelled herein.

Claims 16–22 and 32–38 are amended only as to dependency.

No new matter is introduced as a result of any amendment requested herein.

Respectfully submitted,

James C. Forbes

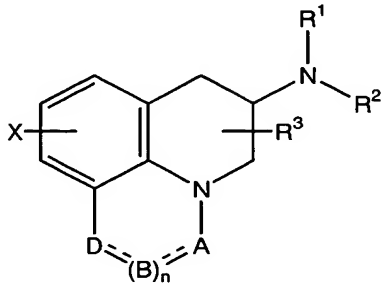
James C. Forbes
Agent for Applicant
Registration No. 39,457
Tel. (847) 581-6090

Address Correspondence to:
Pharmacia Corporation
Patent Department – O4B
800 N Lindbergh Boulevard
St Louis, MO 63167

Attachment
Amended paragraph and claims in marked-up form

Amended paragraph of the specification in marked-up form

International Patent Publication No. WO 00/40226 discloses compounds useful in treating sexual dysfunction in men and women, these compounds being of formula (I)



(I)

or pharmaceutically acceptable salts thereof, wherein

R^1, R^2 and R^3 are the same or different and are H, C_{1-6} alkyl (optionally phenyl substituted), C_{3-5} alkenyl or alkynyl or C_{3-10} cycloalkyl, or where R^3 is as above and R^1 and R^2 are cyclized with the attached N atom to form pyrrolidinyl, piperidinyl, morpholinyl, 4-methylpiperazinyl or imidazolyl groups;

X is H, F, Cl, Br, I, OH, C_{1-6} alkyl or alkoxy, CN, carboxamide, carboxyl or (C_{1-6} alkyl)carbonyl;

A is CH, CH_2, CHF, CHCl, CHBr, CHI, $CHCH_3$, C=O, C=S, $CSCH_3$, C=NH, CNH_2, $CNHCH_3$, $CNHCOOCH_3$, CNHCN, SO_2 or N;

B is CH, CH_2, CHF, CHCl, CHBr, CHI, C=O, N, NH or NCH_3, and n is 0 or 1; and

D is CH, CH_2, CHF, CHCl, CHBr, CHI, C=O, O, N, NH or NCH_3;

with various provisos indicated therein. WO 00/40226 further contemplates prescription of the drug (*R*)-5,6-dihydro-5-(methylamino)-4H-imidazo[4,5-*ij*]-quinolin-2(1H)-one (*Z*)-2-butenedioate (1:1) to male and female subjects at a dose of 1-3 mg, to be taken 0.5-1 h before engaging in sexual activity, and indicates that at such a dose and timing of administration the drug is therapeutically effective. No information is provided as to the [route of administration or] specific nature of dosage form.

Amended claims in marked-up form

1. (Amended) A pharmaceutical dosage form comprising (a) at least one agent effective in treatment of sexual dysfunction having a molecular weight, excluding counterions, not greater than 250, in a therapeutically or sexual-stimulatorily effective total amount, and (b) at least one pharmaceutically acceptable excipient; the dosage form being [adapted for delivery by a route of administration that entails interaction with the organs of taste yet] an oral dosage form selected from the group consisting of fast-melt formulations, breath-freshening pastilles, chewing gums, sublingual tablets, mucoadhesive films and oral strips, and having acceptable organoleptic properties.

16. (Amended) The dosage form of Claim [15] 1 that dissolves in the mouth without need for drinking water or other fluid.

17. (Amended) The dosage form of Claim [15] 1 that is a breath-freshening pastille.

18. (Amended) The dosage form of Claim [15] 1 that is a chewing gum.

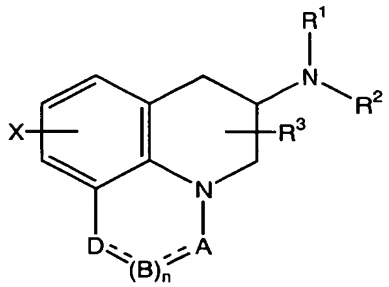
19. (Amended) The dosage form of Claim [15] 1 that is a sublingual tablet.

20. (Amended) The dosage form of Claim [15] 1 that is a mucoadhesive film.

21. (Amended) The dosage form of Claim [15] 1 that is an oral strip.

22. (Amended) The dosage form of Claim [15] 1 that is an oral fast-melt tablet.

23. (Amended) A pharmaceutical dosage form comprising (a) a therapeutically or sexual-stimulatorily effective amount of about 0.1 mg to about 10 mg per dose of a therapeutic agent that comprises at least one compound of formula



or a pharmaceutically acceptable water-soluble salt thereof, said compound or salt thereof being water-soluble, wherein

R^1, R^2 and R^3 are the same or different and are H, C_{1-6} alkyl (optionally

phenyl substituted), C_{3-5} alkenyl or alkynyl or C_{3-10} cycloalkyl, or where R^3 is as above and R^1 and R^2 are cyclized with the attached N atom to form pyrrolidinyl, piperidinyl, morpholinyl, 4-methylpiperazinyl or imidazolyl groups;

X is H, F, Cl, Br, I, OH, C_{1-6} alkyl or alkoxy, CN, carboxamide, carboxyl or (C_{1-6} alkyl)carbonyl;

A is CH, CH_2, CHF, CHCl, CHBr, CHI, $CHCH_3$, C=O, C=S, $CSCH_3$, C=NH, CNH_2, $CNHCH_3$, $CNHCOOCH_3$, CNHCN, SO_2 or N;

B is CH, CH_2, CHF, CHCl, CHBr, CHI, C=O, N, NH or NCH_3, and n is 0 or 1; and

D is CH, CH_2, CHF, CHCl, CHBr, CHI, C=O, O, N, NH or NCH_3;

and (b) one or more pharmaceutically acceptable excipients; the dosage form being [adapted for delivery by a route of administration that entails interaction with the organs of taste yet] an oral dosage form selected from the group consisting of fast-melt formulations, breath-freshening pastilles, chewing gums, sublingual tablets, mucoadhesive films and oral strips, and having acceptable organoleptic properties.

32. (Amended) The dosage form of Claim [31] 23 that dissolves in the mouth without need for drinking water or other fluid.

33. (Amended) The dosage form of Claim [31] 23 that is a breath-freshening pastille.

34. (Amended) The dosage form of Claim [31] 23 that is a chewing gum.

35. (Amended) The dosage form of Claim [31] 23 that is a sublingual tablet.

36. (Amended) The dosage form of Claim [31] 23 that is a mucoadhesive film.

37. (Amended) The dosage form of Claim [31] 23 that is an oral strip.

38. (Amended) The dosage form of Claim [31] 23 that is an oral fast-melt tablet.